

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

WYETH HOLDINGS CORPORATION,)	
WYETH-AYERST LEDERLE LLC, and)	
WYETH LLC,)	
)	
Plaintiffs and Counterclaim-)	
Defendants,)	
)	
v.)	Civ. Action No. 09-955-RGA-CJB
)	
SANDOZ, INC.,)	
)	
Defendant and)	
Counterclaimant.)	

MEMORANDUM ORDER

Pending before the Court in this patent case are two motions to strike expert reports: (1) Sandoz Inc.'s Motion to Strike Expert Report of George G. Zhanel, Ph.D. (D.I. 80, hereinafter "Sandoz's Motion"); and (2) Plaintiffs' Motion Pursuant to Fed. R. Civ. P. 37(c)(1) to Strike the Expert Report of Margaret A. Riley, Ph.D. (D.I. 86, hereinafter "Wyeth's Motion"). For the reasons that follow, the Court GRANTS-IN-PART Sandoz's Motion and DENIES Wyeth's Motion.

I. BACKGROUND

A. Procedural Posture

This case arises from Sandoz's filing of Abbreviated New Drug Application ("ANDA") No. 91-620 with the United States Food and Drug Administration ("FDA"). Sandoz's ANDA seeks to market an injectable form of tigecycline, an antibiotic that Wyeth currently markets under the brand name Tygacil®. (D.I. 1 at ¶ 10) Wyeth first filed suit against Sandoz on

December 11, 2009. (D.I. 1) Wyeth alleges that Sandoz's generic tigecycline product infringes at least one valid claim of U.S. Reissue Patent No. 40,183 ("the '183 patent") and U.S. Patent No. 7,879,828 ("the '828 patent") (collectively, "the patents-in-suit") and seeks a permanent injunction barring Sandoz from manufacturing, using, selling, or offering to sell in the United States, or importing into the United States, any drug product that infringes a valid claim of the patents-in-suit. (*See* D.I. 48)

Sandoz has stipulated that by submitting ANDA No. 91-620, it has committed an act of infringement under 35 U.S.C. § 271(e)(2), and has further stipulated that the commercial manufacture, use, and/or sale of its generic tigecycline antibacterial products would infringe the asserted claims of the patents-in-suit, if any of those claims are found valid and enforceable. (D.I. 62 at 5, ¶ 16; 6, ¶ 24) While conceding infringement, Sandoz challenges the validity of both of the patents-in-suit (*id.* at 7), and asserts that the '828 patent is unenforceable based upon several acts of inequitable conduct (*id.* at 8–17).

Fact discovery closed on October 19, 2011. (D.I. 59) On February 10, 2012, Sandoz filed a single motion for summary judgment of invalidity of the '828 patent for obviousness-type double-patenting. (D.I. 96) Briefing on that motion has not yet been completed. Neither of the expert reports that are the subject of the present motions are cited or otherwise are at issue in Sandoz's summary judgment motion.

On March 5, 2012, this case was reassigned from Judge Leonard P. Stark to Judge Richard G. Andrews, and remains before me on referral to resolve all pre-trial matters. A final pre-trial conference is scheduled for May 11, 2012, and a ten-day bench trial is scheduled to begin on June 4, 2012. (D.I. 23, 41)

B. The Parties' Expert Reports

Although the Scheduling Order in this case has been amended by request of the parties multiple times, the case schedule has always contemplated just three rounds of expert reports: (1) opening reports from the party with the burden of proof on an issue; (2) rebuttal reports; and (3) reply reports. (D.I. 23 at 3) The Court's Scheduling Order provides that "[n]o additional expert reports may be filed without leave of Court or consent of all parties." (*Id.*)

Because there is no dispute regarding infringement, the parties' expert reports focus on the issue of invalidity—an issue for which Sandoz bears the burden of proof.¹ Sandoz timely served its opening expert reports on October 21, 2011, including a report by Jeffrey D. Winkler, Ph.D. (D.I. 82, ex. 2 ("the Winkler Report")) Dr. Winkler, a professor of chemistry at the University of Pennsylvania, opined that the asserted claims of the '183 patent are invalid for lack of enablement, indefiniteness, and lack of written description. (*See id.*) As a rebuttal to Dr. Winkler's opinions, Wyeth timely served a report from Andrew G. Myers, Ph.D., a professor of chemistry at Harvard University, on November 16, 2011. (D.I. 82, ex. 4 ("the Myers Report")) On December 14, 2011, Sandoz served two reports in reply to Dr. Myers—one from Dr. Winkler, and one from Margaret A. Riley, Ph.D., a microbiologist at the University of Massachusetts Amherst (D.I. 82, ex. 5 ("the Riley Report")). This was the first report from Dr. Riley that had been offered by Sandoz. On January 8, 2012, Wyeth served an additional, "sur-rebuttal" expert report from George G. Zhanel, Ph.D., a microbiologist at the University of Manitoba. (D.I. 82, ex. 6 ("the Zhanel Report")) Dr. Zhanel had not previously served an expert report in this case.

¹ See, e.g., *Stamps.com Inc. v. Endicia, Inc.*, 437 F. App'x 897, 907 n.2 (Fed. Cir. 2011) ("[A] party asserting invalidity in a district court always bears the burden of proof by clear and convincing evidence.").

Although numerous issues relevant to the alleged invalidity of the patents-in-suit are discussed in the parties' expert reports, the Riley Report and the Zhanel Report are addressed principally to the question of whether the '183 patent has a written description that satisfies 35 U.S.C. § 112. In particular, the Riley Report and the Zhanel Report both address how the biological data in the '183 patent would have been (and should have been) assessed and evaluated at the time the patent issued.

C. The Parties' Respective Motions to Strike

Sandoz's Motion was filed on January 17, 2012, and requests that the Zhanel Report be stricken, such that Dr. Zhanel would not be permitted to testify at trial. (D.I. 81 at 1) Sandoz asserts that the Zhanel Report violates the Court's Scheduling Order, and that Sandoz would suffer prejudice if Dr. Zhanel is permitted to testify based on this untimely report. (*Id.* at 2) Wyeth opposes Sandoz's motion, arguing that the Zhanel Report was a proper response to certain new microbiological opinions set forth in the Riley Report. (D.I. 87 at 2–3) In the alternative, Wyeth filed its own motion to strike the Riley Report, arguing that if the Court elects to strike the Zhanel Report, then the Riley Report should likewise be stricken. (*Id.* at 13–14)

Briefing on these motions was completed on March 5, 2012 (D.I. 110), and the Court heard further argument from the parties during a teleconference held on March 7, 2012 (D.I. 114). Both motions are ripe for resolution.

II. STANDARD OF REVIEW

The Federal Rules of Civil Procedure require a testifying expert to prepare and sign a written report containing, *inter alia*, "a complete statement of all opinions the witness will express and the basis and reasons for them . . . at the times and in the sequence that the court

orders." Fed. R. Civ. P. 26(a)(2)(B)(i) & (a)(2)(D). "If a party fails to provide information or identify a witness [in the manner required by the Court under Rule 26], the party is not allowed to use that information or witness . . . at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). If an expert report is stricken, that action effectively precludes the expert from testifying as to the subject matter and opinions contained in the report. *See, e.g., Kenexa Brassring, Inc. v. Taleo Corp.*, 751 F. Supp. 2d 735, 759 (D. Del. 2010) (noting that expert "testimony is [generally] limited to subjects addressed in [the expert's] report (or otherwise vetted through expert discovery)"); *Inline Connection Corp. v. AOL Time Warner, Inc.*, 472 F. Supp. 2d 604, 615 (D. Del. 2007) (same).²

Although the Federal Rules clearly contemplate the exclusion of untimely or improper expert disclosures (and the concomitant exclusion of expert testimony), the Third Circuit has cautioned that because "[t]he exclusion of critical evidence is an extreme sanction," it should not be imposed where an untimely or improper expert disclosure amounts to only a "slight deviation from pre-trial notice requirements" or occasions only "slight prejudice" to the movant. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791–92 (3d Cir. 1994) (internal quotation marks and citations omitted). Instead, the remedy of exclusion should be reserved for circumstances amounting to "willful deception or flagrant disregard of a court order by the proponent of the evidence." *Id.* at 792 (internal quotation marks and citation omitted); *see also Bridgestone Sports Co. v. Acushnet Co.*, No. CIV A 05-132 JJF, 2007 WL 521894, at *4 (D. Del. Feb. 15,

² Because the discovery matter at issue here is not unique to patent law, the law of the Third Circuit applies. *See Bridgestone Sports Co. v. Acushnet Co.*, No. Civ. A. 05-132 JJF, 2007 WL 521894, at *4 (D. Del. Feb. 15, 2007) (citing *Micro Chem, Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1390–91 (Fed. Cir. 2003)).

2007) (noting that while the decision to exclude expert testimony is context-specific, "evidence should be excluded sparingly and only in circumstances involving litigation conduct that is clearly unprofessional or inappropriate, and in circumstances creating prejudice to the party against whom the evidence is offered").

In considering whether to exclude expert testimony, the Third Circuit has directed district courts to weigh five factors: (1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply with the court's order; and (5) the importance of the testimony sought to be excluded. *See Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904–05 (3d Cir. 1977), *overruled on other grounds*, *Goodman v. Lukens Steel Co.*, 777 F.2d 133 (3d Cir. 1985); *see also Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997).³ Although district courts tend to err on the side of admitting expert testimony in such cases, this Court has noted that such testimony may be excluded in order to protect against the "flouting of discovery deadlines," so as to maintain "fidelity to the constraints of Scheduling Orders and deadlines[, which] is critical to the Court's case management responsibilities." *Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457, 463 (D. Del. 2005) (internal quotation marks and citation omitted), *rev'd on other grounds*, 543 F.3d 1306 (Fed. Cir. 2008).

III. DISCUSSION

A. Timeliness of the Riley Report & the Zhanel Report

³ Although these factors are sometimes articulated in slightly different ways, they are generally referred to as "the *Pennypack* factors." *See, e.g., Paoli*, 35 F.3d at 792.

Both Wyeth and Sandoz question the timeliness of the opposing side's final expert reports on the issue of written description. Wyeth argues that the content of the Riley Report was not akin to that of a true reply report, and that it therefore should have been served by no later than the deadline for opening expert reports. (D.I. 87 at 9–10) For its part, Sandoz contends that the Zhanel Report was served weeks after the last allowable date for the service of expert reports. (D.I. 81 at 4–5)

1. The Riley Report

The Court first considers whether the Riley Report was served in accordance with the dictates of the Scheduling Order. In that regard, Wyeth argues that it was improper for Sandoz to introduce Dr. Riley's opinions at the expert reply stage. It asserts that serving the report of a "new" expert at that stage contravened the spirit, if not the letter, of the Scheduling Order—particularly where, as here, Dr. Riley's area of expertise (microbiology) differs from that of the experts who had previously issued reports in the case (chemistry). (D.I. 87 at 9–10)

In support of this argument, Wyeth relies on *Oracle America Inc. v. Google Inc.*, No. C 10–03561 WHA, 2011 WL 5572835 (N.D. Cal. Nov. 15, 2011). In that case, plaintiff Oracle, in advance of the deadline to serve opening expert reports, informed the district court that it might serve expert reports from two economists: a Dr. Cockburn and a Dr. Serwin. *Id.* at *2. However, at the deadline for opening reports, Oracle served only a report authored by Dr. Cockburn. *Id.* After defendant Google served its opposition expert reports in response (and after the deadline for filing *Daubert* motions had passed), Oracle then served lengthy reply reports from both Dr. Cockburn and Dr. Serwin. *Id.* Google objected to Dr. Serwin's reply, arguing that it was improper for a "new expert who did not serve any opening report [to] nonetheless make a

reply submission attacking the opposition reports served by the other side." *Id.*

The *Oracle* Court ruled in Google's favor and struck Dr. Serwin's reply expert reports. Although noting that the *Oracle* Scheduling Order did not explicitly limit reply reports to those written by the authors of opening reports, the district court said it "thought this was already clear" and remarked that "in twelve years of using [its form Scheduling Order], this [was] the first time anyone has suggested to the contrary." *Id.* at *3. The district court also noted that the case schedule provided no opportunity for a deposition of a new reply expert, and that there would be no opportunity for an opposing expert to directly respond to Dr. Serwin's reply reports. *Id.*

I believe that the factual circumstances in this case are meaningfully different from those at play in *Oracle*. In *Oracle*, the fact that plaintiff had identified Dr. Serwin as a potential testifying expert prior to the service of opening expert reports—but then withheld any report from him until the reply stage—appears to have contributed to the district court's conclusion that the plaintiff "sandbagged" the defendant by intentionally "sav[ing] its best points for reply." *Id.* In contrast, here there is no similar indication that Sandoz's decision to serve the Riley Report was motivated by such gamesmanship. To the contrary, Sandoz asserts that the motivation to prepare the Riley Report arose only after Dr. Myers made particular arguments in his opposition report, which Sandoz felt were best rebutted by a microbiologist (as opposed to by its expert chemist, Dr. Winkler). (D.I. 100 at 9 ("And unlike the opposition report in *Oracle*, [Wyeth's] opposition report from Dr. Myers for the first time raised issues requiring the expertise of a microbiologist for proper rebuttal."))

The fact that Dr. Serwin (like Dr. Cockburn) was an economist also appears to have contributed to the *Oracle* Court's decision to strike Dr. Serwin's replies, because it was not

evident why Dr. Cockburn would not have himself been qualified to render the same opinions that Dr. Serwin provided, and Oracle made no claim that the issues addressed in Dr. Serwin's replies "might require or be enhanced by some speciality [of his]." *Id.* In contrast, here both parties assert that a particular expertise in microbiology (first introduced by Dr. Riley, and shared by Dr. Zhanel) is important to the assessment of whether the '183 patent is invalid for lack of a sufficient written description. Moreover, unlike the case in *Oracle*, here the Riley Report was served prior to the expiration of the *Daubert* motion deadline, and in sufficient time for Dr. Riley to have been deposed prior to the close of expert discovery.

In this case, while it may have been somewhat unusual, I find that it was not improper for Dr. Riley's first expert report to have been served at the reply stage. The Scheduling Order did not specifically preclude such a filing, and the Court is not aware of (nor have the parties identified) any other local rule or practice that would have prohibited it. *Cf. B. Braun Melsungen AG v. Terumo Med. Corp.*, 749 F. Supp. 2d 210, 221 (D. Del. 2010) (finding that where a scheduling order was "silent" as to whether the parties could file new expert declaration at the summary judgment stage, this counseled against excluding an expert report submitted at that stage in the proceedings, because the report could not be said to have been served in "flagrant disregard" of the order or with willful deception). Indeed, other courts have permitted an expert to serve his or her first report at the reply stage, so long as that report narrowly focused on responding to an opposition report. *See, e.g., Alloc, Inc. v. Pergo, L.L.C.*, No. 00-C-0999, 2010 WL 3808977, at *8–11 (E.D. Wis. Sept. 23, 2010) (denying a motion to strike a reply report served by an expert disclosed for the first time at that stage, where the report was properly and narrowly focused on responding to two discrete issues). Thus, the fact that Dr. Riley did not

serve an opening report does not mean that her reply report violated the Scheduling Order.

Wyeth's other argument is that the *content* of the Riley Report demonstrates that it was not the subject of a proper reply. In this regard, Wyeth alleges that the Riley Report "introduced a new analysis of the '183 patent microbiological data, allegedly in support of Sandoz's contention that the '183 patent claims are allegedly invalid for lack of written description." (D.I. 87 at 10) Wyeth asserts that "[t]hese opinions are directed to the same written description defense and some of the very same . . . data about which Dr. Winkler opined." (*Id.*) As such, Wyeth contends that "Dr. Riley's opinions should have been included in an opening report." (*Id.*)

After reviewing the content of the expert reports submitted by the parties in connection with their motions, the Court concludes that the Riley Report was a proper reply to the Myers Report. The Riley Report is seven pages long and consists primarily of a two-pronged critique of a specific line of argument from the Myers Report. First, Dr. Riley notes Dr. Myers' conclusion that a person of ordinary skill in the art would "evaluate . . . compounds as a class, rather than individually, when considering the various modifications that might present advantages for antibacterial activity." (D.I. 82, ex. 5 at ¶ 24) In Dr. Riley's view, Dr. Myers then arbitrarily selected *individual* compounds and *individual* bacterial strains to analyze as part of this evaluation process. (*Id.* at ¶¶ 25–27) Dr. Riley contends that Dr. Myers should have examined "the activity of candidate compounds against a wide range of strains," rather than just against selected individual strains. (*Id.* at ¶ 30) Second, Dr. Riley argues that if a person of ordinary skill in the art was pursuing the class-based approach advocated by Dr. Myers, then that person would have analyzed the average Minimum Inhibitory Concentration ("MIC") for the classes of

strains.⁴ (*Id.*)

The Riley Report thus focuses narrowly on critiquing the approach set forth in a portion of the Myers Report. Indeed, in her analysis, Dr. Riley repeatedly cites to the corresponding paragraphs of the Myers Report with which she takes issue. (*Id.* at ¶¶ 24–26 (citing paragraphs 80–114 of the Myers Report)) The first time that it was possible for Sandoz and Dr. Riley to respond to Dr. Myers was at the expert reply stage. *See, e.g., Hans v. Tharaldson*, Civil No. 3:05-cv-115, 2011 WL 6937598, at *10 (D.N.D. Dec. 23, 2011) (noting that "[t]he function of rebuttal evidence is to explain, repel, counteract or disprove evidence of the adverse party" and that "[e]xperts are typically allowed to introduce new methods of analysis in a rebuttal report if they are offered to contradict or rebut another party's expert") (internal citations and quotation marks omitted). It does appear to be the case, as Wyeth contends, that Dr. Riley's opinions "are directed to the same written description defense and some of the very same MIC data about which [Sandoz opening expert report author] Dr. Winkler opined; they simply approach them from a different perspective." (D.I. 87 at 10) But the motivation to approach the data from this "different perspective" only arose in response to the particular way that data was analyzed in the Myers Report. That type of motivation goes to the heart of what constitutes a proper reply. As such, the Riley Report was timely and properly served.

2. The Zhanel Report

Sandoz argues that "[t]here can be no dispute that Dr. Zhanel's report is untimely." (D.I. 81 at 4) Wyeth does not directly dispute that the Zhanel Report was served outside the time

⁴ "MIC" refers to the lowest concentration of a compound that inhibits growth of the test organism. (D.I. 1, ex. A at col. 95:45–55)

limits established by the Scheduling Order, but instead argues that the alleged untimeliness of the Riley Report and the lack of prejudice to Sandoz from the Zhanel Report justifies its late service.

(D.I. 87 at 11)

Under the Court's Scheduling Order, all expert reports were to have been served by no later than December 14, 2011, with expert discovery closing on February 3, 2012. (D.I. 59 at 2; D.I. 74 at 2) The Zhanel Report, although served before the close of expert discovery, was nonetheless served more than three weeks after the date that the last expert reports were required to be served. Moreover, the Scheduling Order specifically prohibited service of any reports beyond the reply stage, absent "leave of Court or consent of all parties." (D.I. 23 at 3) When Wyeth served Dr. Zhanel's report on Sandoz, Wyeth did not have Sandoz's consent to file a "sur-rebuttal" report, nor did it have leave of the Court to do so.

In light of these facts, the Court finds that the Zhanel Report is untimely under the Scheduling Order. However, that finding does not resolve the question of whether Wyeth's noncompliance was harmless or was substantially justified, such that Dr. Zhanel should nonetheless be permitted to testify at trial. To make this determination, the Court must analyze the Zhanel Report in light of the *Pennypack* factors.

B. Applying the *Pennypack* Factors to the Zhanel Report

1. The Content of the Zhanel Report

In order to analyze how the *Pennypack* factors should apply to the Zhanel Report, it is helpful to first examine the content of that report.

As noted above, the Riley Report criticizes the Myers Report in a limited number of respects, by arguing that (1) Dr. Myers' focus on analyzing antimicrobial candidate compounds

against only particular bacterial strains was improper, because a person of ordinary skill in the art would look to a broader class of microbiological data; and that (2) if a person of skill in the art were to generally follow Dr. Myers' approach, that person would look to average MIC values to analyze the various compounds.

The Zhanel Report, after providing background information about Dr. Zhanel (*see* D.I. 82, ex. 6 at ¶¶ 1–13), then sets forth a summary of his opinions (*see id.* at ¶¶ 14–18). Much of that summary responds to Dr. Riley's assertions. In particular, Dr. Zhanel claims that Dr. Riley mischaracterized Dr. Myers' approach, and that a person of skill in the art would not have calculated mean MIC values or analyzed those values in the manner suggested by Dr. Riley. (*See id.* at ¶¶ 17, 18)

Next, after setting forth his understanding of the level of ordinary skill in the art (*id.* at ¶¶ 19–20), Dr. Zhanel provides a lengthy "Technology Overview" that does not appear to respond to any information or opinions in the Riley Report (*id.* at ¶¶ 21–32). However, this information simply provides context and background for the opinions that Dr. Zhanel will later offer. As such, it is more along the lines of "[a] technology and terminology tutorial," which even Sandoz has acknowledged is not particularly objectionable in this context, as it does not "pertain to issues for which [either] party bears the burden of proof." (D.I. 100 at 5)

Dr. Zhanel next offers context for his first opinion, which is that "Dr. Riley mischaracterize[d] Dr. Myers'[] analysis" when she asserted that Dr. Myers wrongly focused only on biological activity against one particular bacterial strain. To the contrary, Dr. Zhanel concludes, Dr. Myers was simply highlighting the results against that particular strain as one example of a broader approach to identifying preferred sets of compounds. (D.I. 82, ex. 6 at ¶¶

33–36) This portion of the Zhanel Report directly responds to corresponding arguments in the Riley Report. Dr. Zhanel then offers his opinion that "microbiologists would not pool or average data across bacterial strains," as Dr. Riley suggested in her report, but instead would evaluate the classes of novel compounds against "[e]ach strain" listed in Tables I through V of the '183 patent. (*Id.* at ¶¶ 37–39; *see also* ¶ 40) This portion of Dr. Zhanel's analysis also is clearly responsive to Dr. Riley's critiques, as it disputes Dr. Riley's opinion that a microbiologist (in contrast to a chemist) would approach the '183 patent in a different way than Dr. Myers did.

However, Dr. Zhanel then undertakes a lengthy analysis of several asserted claims of the '183 patent, peppered with multiple points of agreement with Dr. Myers. (*Id.* at ¶¶ 40–85) This section of the Zhanel Report appears to be what Sandoz calls "an entirely new validity analysis" that is largely "a recitation of all the reasons [Dr. Zhanel] believes Dr. Myers is correct." (D.I. 81 at 7–8) Dr. Riley is almost never mentioned in this portion of the Zhanel Report. Instead, in these paragraphs, Dr. Zhanel offers detailed characterizations and conclusions regarding the data of the '183 patent, going so far as to provide a claim-by-claim analysis of that patent rather than merely contradicting the validity of the criticisms in the Riley Report.

With the content of the Zhanel Report in mind, the Court now considers how the *Pennypack* factors apply in the present circumstances.

2. The *Pennypack* Factors

a. Surprise/Prejudice

The Court first considers the extent to which the Zhanel Report came as a surprise to Sandoz or would otherwise prejudice Sandoz, and whether any such prejudice could be cured. *Pennypack*, 559 F.2d at 904. First, Sandoz claims that the "surprise disclosure" by Dr. Zhanel

"has prejudiced [it] . . . [with] the time and expense of a two-month impact on the case schedule."

(D.I. 81 at 1, 5) Sandoz argues that it has been and will be prejudiced if Dr. Zhanel's testimony is permitted because: (1) Sandoz had to spend time and money reviewing the Zhanel Report and briefing the instant motions; (2) if the Zhanel Report is not stricken, Sandoz will have to prepare for and depose Dr. Zhanel; (3) in such a circumstance, Drs. Winkler and Riley will also need to prepare new reply reports; and (4) Dr. Winkler had "virtually no time to review the [Zhanel] [R]eport and include it in his deposition preparation." (*Id.* at 5; D.I. 100 at 6)

As to the "surprise" nature of the Zhanel Report, Sandoz's claims are not strong. The fact that Wyeth served a "sur-rebuttal" report from Dr. Zhanel should not have come as a great surprise to Sandoz. Although the Riley Report was not precluded by the Scheduling Order, the filing of a reply report from a new expert (especially one in a different field of expertise from that of prior experts) is, as the *Oracle* Court noted, an unusual occurrence. Sandoz should reasonably have expected that introducing Dr. Riley's opinions at that stage of expert discovery, in that manner, was bound to produce some response from Wyeth. Indeed, the Riley Report seems to suggest as much, given Dr. Riley's acknowledgment that "Wyeth may serve an expert report concerning one or more of the issues addressed [in her] report." (D.I. 82, ex. 5 at ¶ 4)

Moreover, as to Sandoz's claims of prejudice regarding the Zhanel Report's impact on its resources and on the case schedule, any such impact can be largely mitigated. It is true that allowing some portion of the Zhanel Report would extend the expert discovery period for a moderate length of time, in order to accommodate the deposition of Dr. Zhanel (along with that of Dr. Riley). In addition to the money it has expended regarding the instant motions, Sandoz will also face moderate additional expense associated with Dr. Zhanel's deposition, which would

be avoided if his testimony was excluded entirely. However, Wyeth has repeatedly represented that it will promptly make Dr. Zhanel available for a deposition (*see, e.g.*, D.I. 87 at 12), and given the current posture of this case, there is still ample time for that deposition to take place. Sandoz's ability to depose Dr. Zhanel well before trial will help mitigate any surprise or prejudice it might have faced due to the late receipt of his report.⁵ Similarly, the time remaining before the June 2012 trial will likely allow the parties to find a time and venue for the deposition that is convenient to Sandoz, which should minimize any associated expenses.

Lastly, contrary to Sandoz's claim, the Court does not believe that allowing some portion of the Zhanel Report would justify the filing of additional reply reports from Dr. Winkler or Dr. Riley. The Zhanel Report (with the exception of paragraphs 40–85), does not directly respond to the Winkler Report, but instead is focused on criticizing Dr. Riley's limited methodological analysis. Moreover, as Sandoz itself has acknowledged, Dr. Riley's report is directed to the "usual analytical framework used by *microbiologists*." (D.I. 81 at 7 (emphasis added)) Because Dr. Winkler is a chemist, not a microbiologist, any further report from him would be from a different perspective as that provided by Drs. Riley and Zhanel, which lessens the need for such a

⁵ Courts have regularly found that when there is sufficient time for the opposing party to depose an expert who serves an untimely report, this militates in favor of allowing the expert's testimony. *Compare Paoli*, 35 F.3d at 792 (finding district court erred in excluding untimely expert submission where the specifics of expert's testimony was provided to defendants four months before trial and 60 days before end of expert discovery, giving defendants "abundant time to depose" the expert before the discovery deadline) and *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, No. C.A. 04-1371-JJF, 2006 WL 2435083, at *1 (D. Del. Aug. 22, 2006) (rejecting a party's claim that it would be prejudiced by a supplemental expert report where the party had almost three weeks to review the report before having the opportunity to depose the expert), *with Praxair*, 231 F.R.D. at 463 (excluding supplemental expert report regarding summary judgment motions, but only where the "report was filed ten days before the summary judgment motions were due, so plaintiffs had no opportunity to conduct rebuttal discovery" for the motions).

report, at least at this juncture.⁶ Moreover, Sandoz has not identified a sufficient justification for Dr. Riley to serve another report, particularly given that Dr. Riley has not yet been deposed. In light of the additional findings and conclusions set forth below, the Court believes that a deposition will likely offer Dr. Riley the opportunity to appropriately respond to Dr. Zhanel's opinions and elaborate on her own opinions from her report.

Sandoz's second claim of prejudice is addressed to the content of the Zhanel Report. Sandoz argues that allowing Dr. Zhanel to testify about paragraphs 40–85 of his report would cause it prejudice, because those paragraphs "go[] well beyond merely responding to [the Riley Report]," and instead are cumulative of Dr. Myers' opinions and provide "new, alternate grounds to support [those] opinions." (D.I. 81 at 8; D.I. 100 at 1, 3) I agree that permitting Dr. Zhanel to testify regarding these paragraphs of his report would cause prejudice to Sandoz, in a way that permitting his testimony on the remaining topics of the Zhanel Report would not.

Paragraphs 1–39 of the Zhanel Report provide:⁷ (1) necessary background information on Dr. Zhanel; (2) a helpful summary of the relevant technology at issue; or (3) a direct, specific response to Dr. Riley's criticisms of Dr. Myers. For the reasons set forth above, Sandoz would be subject to minimal prejudice, at most, were it required to now marshal the resources necessary to

⁶ Similarly, although Sandoz complains that the late service of the Zhanel Report gave Dr. Winkler little time to review that report prior to his deposition, Sandoz does not specify how Dr. Winkler's deposition testimony was compromised as a result. In the absence of the articulation of such prejudice, the Court is not convinced that an additional report from Dr. Winkler is warranted at this stage.

⁷ Paragraph 40 of the Zhanel Report primarily provides a summary of Dr. Zhanel's view of Dr. Riley's opinions. However, it is located in a section of the Zhanel Report (section IV.C) that otherwise focuses on a claim-by-claim analysis of the '183 patent. In restricting the Zhanel Report to paragraphs 1–39, I do not mean to exclude Dr. Zhanel from summarizing his opinions, consistent with the first four sentences of paragraph 40.

confront this limited, focused portion of the Zhanel Report. Moreover, these specific portions of the Zhanel Report are true rebuttal (albeit rebuttal not explicitly permitted by the Scheduling Order), in that they are a clear response to arguments made in Dr. Riley's reply.

However, in paragraphs 40–85 of his report, Dr. Zhanel conducts an extensive analysis of claims 2 and 99–103 of the '183 patent, repeatedly emphasizing the ways in which he agrees with Dr. Myers' view of those same claims. These paragraphs do not directly respond to the specific arguments made in the Riley Report⁸ regarding Dr. Myers' use of individual bacterial strains to analyze certain compounds, nor to Dr. Myers' failure to analyze the mean MICs of various compounds.⁹ Were Dr. Zhanel permitted to provide the type of broad testimony suggested in these paragraphs, the impact would be, as Sandoz suggests, tantamount to having "an additional expert witness to testify to the correctness of another expert's opinions." (D.I. 81 at 8); *cf. Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 763 F. Supp. 2d 671, 692 (D. Del. 2010) (allowing service of an additional rebuttal expert report, but only so long as it was "solely devoted to" the opinions that were introduced by the opposing expert). This type of wide-ranging analysis should have been provided at the opposition report stage—and indeed was provided, in significant part, by Dr. Myers.¹⁰ Allowing Dr. Zhanel to opine on the contents of these many

⁸ Dr. Riley did not interpret the data of the '183 patent, nor undertake a claim-by-claim analysis of the patent. Instead, she confined her report solely to a discussion of particular *methods* that a microbiologist would (or would not) have applied to that data.

⁹ Indeed, at oral argument, counsel for both parties agreed that paragraphs 33 to 39 of the Zhanel Report were more explicitly directed to the core of Dr. Riley's analysis than were the remaining paragraphs of the Zhanel Report. (D.I. 114 at 25, 45–46)

¹⁰ This is underscored by the sheer number of times in paragraphs 40–85 of the Zhanel Report that Dr. Zhanel either summarizes or agrees with Dr. Myers' approach, or cites the Myers Report. (*See, e.g.*, D.I. 82, ex. 6 at ¶¶ 40–48, 56, 60–63, 69, 75, 83–85)

paragraphs would require Sandoz to outlay significant additional resources in response.

Moreover, it would create an imbalance at trial, giving Wyeth two experts (to Sandoz's one) to provide claim-by-claim analyses of the '183 patent in connection with Sandoz's written description defense, even though one of those experts (Dr. Zhanel) did not file a timely report.

For the foregoing reasons, the *Pennypack* factors relating to surprise and prejudice weigh in favor of allowing testimony based on paragraphs 1–39 of the Zhanel Report, but not based on the remaining paragraphs of that report.

b. Potential Disruption to Trial

The next *Pennypack* factor requires the Court to assess whether allowing testimony based upon the Zhanel Report would potentially disrupt the trial proceedings. 559 F.2d at 904. As outlined in the preceding subsection, trial is months away, and the scope of that trial is still in flux. For instance, briefing on Sandoz's motion for summary judgment will not even be complete until later this month, and no motions *in limine* have yet been filed. Although both parties will need to prepare for expert testimony from Drs. Riley and Zhanel at trial, there is sufficient time to do so, especially if the scope of that testimony is appropriately cabined.¹¹ This is particularly true given that, unlike the typical patent case, which is tried to a jury and involves contested issues of infringement, this case is scheduled for a bench trial—where only issues of invalidity and enforceability could be contested. (D.I. 23 at 7) Given the streamlined nature of these proceedings (and Sandoz's failure to identify any specific disruption to trial that would likely occur), the Court finds that this factor weighs in favor of allowing Dr. Zhanel to testify in

¹¹ Cf. *Praxair*, 231 F.R.D. at 463 (excluding supplemental expert report in circumstance where allowing additional discovery would "undoubtedly disrupt the trial process, [which was] set to begin in less than a month").

response to Dr. Riley's opinions.

c. Alleged Bad Faith or Willfulness

The Court must also assess whether Wyeth acted willfully or in bad faith by serving the Zhanel Report in contravention of the Court's Scheduling Order. 559 F.2d at 904–05. Sandoz does not explicitly use the term "bad faith" to describe Wyeth's service of the Zhanel Report. However, Sandoz does state that "while the parties spent weeks negotiating the expert deposition schedule after Sandoz served its rebuttal reports . . . [Wyeth] never disclosed [its] intent to serve" the Zhanel Report; it thus accuses Wyeth of making a "calculated decision" to "spring Dr. Zhanel's report on Sandoz." (D.I. 81 at 4–5) Wyeth strongly disputes this characterization, arguing that but for Sandoz's service of the Riley Report, "Wyeth would not have needed to submit . . . a rebuttal report from its own microbiology expert." (D.I. 87 at 11) Wyeth contends that rather than "intentionally withholding Dr. Zhanel's report, [it] responded as quickly as it reasonably could" to the Riley Report. (*Id.*) Wyeth represents that it had not planned to serve a report from its own microbiologist until receiving the Riley Report, did not contact Dr. Zhanel until after the Riley Report was served on December 14, 2011, and offered to make Dr. Zhanel available for a deposition before the close of expert discovery. (*Id.* at 12)

The Court discerns no evidence that Wyeth acted willfully or in bad faith by serving the Zhanel Report when it did. Although the parties may dispute whether the issue of how a microbiologist would interpret the data of the '183 patent should have been raised earlier, the first time it arose was in the context of Dr. Riley's report. As previously noted, it is understandable that Wyeth may have been surprised by Dr. Riley's entrance into the case. And it appears that it was the Riley Report—not any intentional effort to surprise Sandoz—that motivated Wyeth to

seek Dr. Zhanel's response. As such, the lack of any discernible bad faith on the part of Wyeth weighs in favor of permitting at least those portions of the Zhanel Report that truly rebut the Riley Report. *See, e.g., Johnson v. Portz*, 707 F. Supp. 2d 494, 499 (D. Del. 2010) (allowing testimony from a witness where there was "no indication of bad faith on the part of" the proponents of the testimony, which was first identified in response to late-raised issues, and where the testimony "[did] not represent a significant portion of the case").

d. Importance of Testimony from Dr. Zhanel

The final *Pennypack* factor directs the Court to analyze the importance of the testimony from Dr. Zhanel to Wyeth. 559 F.2d at 904. Testimony from technical experts is often of paramount importance in patent cases. *See, e.g., Hewlett-Packard Co. v. EMC Corp.*, 330 F. Supp. 2d 1087, 1098 (N.D. Cal. 2004) (noting that "in high-technology patent infringement cases . . . the courts, as well as the public, rely on experts to explain complicated technologies"). Indeed, Wyeth asserts that it would suffer "extreme prejudice" if the Court strikes the Zhanel Report, whereby Dr. Riley's opinions would be "immunize[d] . . . from challenge by Wyeth." (D.I. 87 at 4, 13) Wyeth contends that Dr. Zhanel's testimony is essential because it "will allow for a complete airing by both parties of all the issues . . . [thus] providing the Court with a complete record on which to base its decision" in this case. (*Id.* at 13 (emphasis in original omitted))

For the reasons set forth above, the Court agrees with Wyeth that testimony from Dr. Zhanel—insofar as it responds directly to Dr. Riley's specific critiques—will be important to Wyeth at trial. Without Dr. Zhanel's testimony, Wyeth would be unable to try to rebut Dr. Riley's specific criticisms of Dr. Myers from a microbiological perspective. It is also likely to be

important to the Court, which would then have the benefit of opposing microbiological viewpoints when assessing the data of the '183 patent.¹² On the other hand, any testimony by Dr. Zhanel based upon paragraphs 40–85 of his report appears to be largely cumulative of Dr. Myers' conclusions. Such testimony would not have significant importance at trial, particularly because its substance could be conveyed in large part by another expert witness.

As with the other *Pennypack* factors, the importance of Dr. Zhanel's testimony in response to Dr. Riley weighs against the "extreme sanction" of striking the entire Zhanel Report.

e. Conclusion

In light of the analysis set forth above, the Court finds that although the Zhanel Report was untimely, the *Pennypack* factors weigh in favor of permitting Dr. Zhanel to testify about the subjects set forth in paragraphs 1–39 of his report. However, those same factors also counsel in favor of granting Sandoz's motion to strike paragraphs 40–85 of the Zhanel Report, and prohibiting Dr. Zhanel from testifying as to the content of those paragraphs. In light of its decision to strike those portions of the Zhanel Report that extend beyond the scope of the Riley Report, the Court finds no basis for Sandoz's request to serve "additional reply reports from Dr. Winkler and Dr. Riley."¹³ (D.I. 100 at 10 n.3) The Court likewise finds no basis to award

¹² Neither party has objected to the credentials or relevance of the testimony sought to be offered by Dr. Riley or Dr. Zhanel pursuant to the principles in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Under the Court's Scheduling Order, the deadline for making such motions has passed. (D.I. 23 at 3) Although the Court notes that Dr. Winkler opined that the art of the '183 patent is "multidisciplinary, spanning organic chemistry, medicinal chemistry, and microbiology," (D.I. 82, ex. 2 at ¶ 23), the issue of whether Drs. Riley and Zhanel (or any other experts that have served reports in this case) are appropriately considered persons of skill in the art of the '183 patent is not before the Court.

¹³ This decision does not alter the obligation of all parties to supplement their expert disclosures as required by Fed. R. Civ. P. 26(e)(2).

Sandoz any costs associated with the filing of its motion or with deposing Dr. Zhanel, given the limited nature of the Zhanel Report (as modified by this Order), the ample time remaining for Sandoz to schedule and prepare for Dr. Zhanel's deposition, and the other considerations discussed in this Order.

IV. CONCLUSION

For the foregoing reasons, it is hereby ORDERED that Sandoz's motion is GRANTED-IN-PART and that Wyeth's motion is DENIED. Dr. Riley will be permitted to testify based upon her report, as served on December 14, 2011. Dr. Zhanel will be permitted to testify only as to those portions of his report that are directly responsive to Dr. Riley's report, as outlined above.

Because this Memorandum Order may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single jointly proposed redacted version (if necessary) of the Memorandum Order. Any such redacted version shall be submitted no later than **March 21, 2012** for review by the Court. The Court will subsequently issue a publicly-available version of its Memorandum Order.

Dated: March 14, 2012



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE